

Exhibit A

Christina K. Pramudji, M.D.

1 IN THE UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

- - -

4 IN RE: ETHICON, INC., PELVIC : MASTER FILE NO.
5 REPAIR SYSTEM PRODUCTS :: 2:12-MD-02327
6 LIABILITY LITIGATION :
7 : NO. 2327
8 THIS DOCUMENT RELATES TO: : CASE NO.
9 DIANNE M. BELLEW, :: 2:13-CV-22473

- - -

10 September 17, 2014

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11 Videotaped deposition of CHRISTINA K. PRAMUDJI,
12 M.D., taken pursuant to notice, was held at the Westin
13 Galleria, 5060 West Alabama, Street, Houston, Texas, beginning
14 at 10:24 a.m., on the above date, before Mary Kay Hendricks,
15 CSR, a Registered Professional Reporter, Certified Shorthand
16 Reporter.
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1 the FDA that specify what type of information is
2 supposed to be found in warnings for the products like
3 the Prolift, correct?

4 MR. SNELL: Form.

5 A. No, I'm not.

6 Q. (BY MR. SLATER) You're not familiar with the
7 internal standards at Ethicon that the medical affairs
8 and regulatory affairs people followed in terms of what
9 information needed to be in the IFU and the patient
10 brochure and other documents about the Prolift, correct?

11 A. That's correct. I don't know that.

12 Q. In drawing (sic) your opinions, you did not
13 rely on any internal standards or any deposition
14 testimony by any Ethicon witness as to what information
15 needed to be in the IFU, the patient brochure or any
16 other document about the Prolift, correct?

17 MR. SNELL: Form.

18 A. I don't -- I don't believe I did, not that I
19 can recall off the top of my head, no.

20 Q. (BY MR. SLATER) You do not know what the
21 requirements were that Ethicon had to satisfy before
22 they could market the Prolift, do you?

23 A. No, I don't.

24 Q. You do not know what was considered by the
25 Ethicon medical affairs director at the time that she

1 Q. (BY MR. SLATER) If Ethicon misrepresented
2 information in the patient brochure, you would criticize
3 that, right?

4 A. Yes.

5 Q. You would criticize that because that would be
6 misleading to doctors and patients, correct?

7 MR. SNELL: Form.

8 A. Correct.

9 Q. (BY MR. SLATER) And you would criticize that
10 because that could have an impact on patients' safety,
11 correct?

12 MR. SNELL: Form.

13 A. It could have -- it could have an impact on
14 patient safety, yes.

15 Q. (BY MR. SLATER) Do you know what the purpose
16 of the IFU is from the perspective of Ethicon?

17 A. From the perspective of Ethicon, no. I have my
18 perspective as a surgeon.

19 Q. Do you know what the purpose of the IFU is
20 pursuant to FDA regulations?

21 A. No.

22 Q. Do you know the standards that apply to what
23 information is supposed to be in the patient brochure?

24 A. No, I don't.

25 Q. Do you know what FDA regulations would require

Christina K. Pramudji, M.D.

1 you would want to have known that, correct?

2 MR. SNELL: Form.

3 A. I mean, I don't -- I mean, they did provide
4 some guidance to that, and a lot of it was intuitive
5 surgical principles. So I don't know that they would
6 have added anything to -- to what I would have done, my
7 decision making, how I used the product.

8 MR. SLATER: Move to strike --

9 A. So I would say "no." The answer would be "no."

10 MR. SLATER: Okay. Move to strike.

11 Q. (BY MR. SLATER) If Ethicon thought that there
12 were certain women as to whom caution needed to be shown
13 based on information that Ethicon had, would you have
14 wanted them to share that information so you could
15 consider it?

16 MR. SNELL: Form.

17 A. Yes, I would.

18 Q. (BY MR. SLATER) Your level of knowledge and
19 experience would not be the same as all physicians
20 considering using the Prolift, correct?

21 A. That's correct.

22 Q. So simply saying that doctors would understand
23 something or know something, you -- leaves questions as
24 to what different doctors know. Let me rephrase it.
25 You don't know the level of experience and knowledge of

1 each doctor that considered using the Prolift. You
2 haven't studied that question, right?

3 A. No. That would be impossible to know.

4 Q. And in providing warnings and information, you
5 wouldn't want to assume that all physicians would have
6 the same level of knowledge and experience as you would
7 have, right?

8 A. Well, I think the IFU clearly states that it's
9 designed for pelvic surgeons that are familiar with the
10 pelvic -- with pelvic surgery. So I think we're
11 starting with a baseline knowledge.

12 Q. Okay. Familiar with pelvic surgery with mesh.
13 How many surgeries does that mean? Is there a defined
14 number?

15 A. No, there's not a defined number.

16 Q. A doctor could do one procedure with mesh and
17 think that he or she is familiar with that type of
18 surgery, correct?

19 A. I suppose a doctor could assume that. Yeah,
20 some -- some doctors --

21 Q. So saying that doctors need to be familiar with
22 surgery with mesh really doesn't tell you anything about
23 the level of knowledge and experience the doctor needs
24 to have, correct?

25 A. I mean, you're -- it's common sense basically

1 that if there's a -- if you go through training and you
2 have been trained on pelvic surgery in residency or
3 after fellowship, then -- then you have a knowledge of
4 pelvic surgery. I mean, it's obvious common sense that
5 if you just do one that you're not familiar with it
6 whether a doctor thinks that or not.

7 Q. Telling doctors that they need to be familiar
8 with pelvic surgery does not tell the doctor
9 specifically what their level of knowledge and
10 experience needs to be. It's not defined, correct?

11 A. Yes. It's not defined. It's not specific.
12 You're correct.

13 Q. And, in fact, sales representatives are paid
14 more money when they can get more doctors in their
15 territory interested in using a product and procedure
16 like the Prolift, right?

17 MR. SNELL: Form.

18 A. I don't know how they're paid.

19 Q. (BY MR. SLATER) Well, I think you assume that
20 sales representatives get more money based on generally
21 more sales from the doctors and facilities in their
22 territory. Okay --

23 A. Okay. I'll grant you that.

24 Q. That would give the sales representatives an
25 incentive to bring doctors in for training regardless of